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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,665	09/09/2003	Doug Holc	0-03-192	2000

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EXAMINER	
DEAK, LESLIE R	
ART UNIT	**PAPER NUMBER**
3761	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
30 DAYS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of Non-Compliant Amendment (37 CFR 1.121)	Application No. 10/658,665	Applicant(s) HOLE ET AL.	
	Examiner Leslie R. Deak	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The amendment document filed on 22 January 2007 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
  - ☐ A. Amended paragraph(s) do not include markings.
  - ☐ B. New paragraph(s) should not be underlined.
  - ☐ C. Other _____.
- ☐ 2. Abstract:
  - ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
  - ☐ B. Other _____.
- ☐ 3. Amendments to the drawings:
  - ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
  - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
  - ☐ C. Other _____.
- ☐ 4. Amendments to the claims:
  - ☐ A. A complete listing of all of the claims is not present.
  - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
  - ☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
  - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
  - ☐ E. Other: _____.
- ☒ 5. Other (e.g., the amendment is unsigned or not signed in accordance with 37 CFR 1.4):
  Applicant failed to elect a single claimed invention for prosecution on the merits

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714.

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

1. Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted.

2. Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the correction, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action. If any of above boxes 1. to 4. are checked, the correction required is only the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121.

   Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

   Failure to timely respond to this notice will result in:
   Abandonment of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or
   Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

_____ _____

Legal Instruments Examiner (LIE), if applicable Telephone No.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, drawn to a method of reducing pathogens in a mammal's blood by creating an extracorporeal blood circuit and exposing the blood to nitric oxide in the circuit, classified in class 604, subclass 23.

II. Claims 4-14, drawn to a method of to a method of reducing pathogens in a mammal's blood by creating an extracorporeal blood circuit with an oxygenator and oxygenating the blood and exposing the blood to nitric oxide in the circuit, classified in class 604, subclass 6.14.

III. Claims 15-20, drawn to a device for treating blood comprising an extracorporeal circuit, a pump, a nitric oxide unit, and a scavenger unit, classified in class 422, subclass 44.

IV. Claims 21-35, drawn to a method for reducing pathogens in a mammal's blood by providing nitric oxide via respiratory device, classified in class 128, subclass 200.24.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions in Groups I, II, and IV are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant

case, the inventions as claimed have a materially different mode of operation. In Group I, the claimed process includes only administration of nitric oxide in an extracorporeal circuit. In Group II, the process comprises the steps of administering nitric oxide in an extracorporeal circuit and the step of oxygenating the blood. In Group IV, the process excludes the creation of an extracorporeal circuit, administering nitric oxide via a nasal passage. Since each of the claimed sets of processes comprise steps not included in the other claimed processes, each process has a different mode of operation. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

3. Inventions in Groups I, II, and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the processes as claimed may be performed by a materially different apparatus, since neither claimed process comprises any step associated with scavenging free radicals. The apparatus comprises a free radical scavenger not used by the claimed processes, therefore indicating that the processes can be practiced by a different apparatus.

4. Inventions in Group III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not capable of use together, since the process claimed

in group IV does not use an extracorporeal circuit as set forth in the apparatus claim, and the extracorporeal circuit claimed in Group III lacks any components to perform the respiratory therapy of Group IV.

5. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Response to Amendment

8. The reply filed on 22 January 2007 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s): Applicant failed to select a **single** claimed invention for prosecution on the merits. See 37 CFR 1.111. Since the above-mentioned reply appears to be *bona fide*, applicant is given **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

9. Applicant selected three distinct groups for examination, while the restriction requirement allows applicant to select only **one** invention for prosecution. Applicant argues that a search of devices for treating the blood with nitric oxide will necessarily include extracorporeal circuits. Nitric oxide treatment may comprise a separate withdrawal system, treatment system, and infusion system, that may not be combined as a single extracorporeal circuit. Examiner further notes that the restriction requirement was based on the additional components of the circuit, such as the oxygenator and the scavenger unit.

10. Applicant is directed to select a **single** claimed invention for prosecution on the merits.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
15 March 2007